EVOLVING AND IMPLEMENTING A RATIONAL DRUG POLICY WITH A STUDY ON RATIONAL DRUG USE IN A TEACHING HOSPITAL

SUBMITTED IN PARTIAL FULFILLMENT
OF THE FINAL EXAMINATION OF
POST-GRADUATE DIPLOMA IN
HEALTH CARE ADMINISTRATION

BY

FR. DR. PATRICK PAIS SVD

HEALTH CARE ADMINISTRATION
ST. JOHN'S MEDICAL COLLEGE HOSPITAL
BANGALORE

August — 1990

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P R E F A C E

Drugs are the hallmark of Modern Medicine. Throughtout the ages the healers have used both natural and sythetic products for their medicinal value. Drugs, however, have never dominated medical scene as they have done in the second half of this century. We are at the thresh-hold of 21st. century and we are committed to the goal, "Health for All by 2000 A.D.". It is important for all to realise the importance of essential drugs concept. In the recent years there has been considerable interest in developing a conceptual framework leading to formulation and implementation of policies and programmes for promoting rational use of drugs on the basis of this concept.

One has to see that this conceptual framework leading to formulation and implementation is totally unbiased and free from external influence.

In this paper, I have tried in a small way, to evolve a Rational Drug Policy and to find out ways and means of implementing it. An attempt is also made to understand the prescription habits of doctors and to see how an improvement in prescription habit could lead to rational drug use.

Many people have generously helped me in the preparation of this paper. I am thankful to all of

them. I gratefully place on record the direction and quidance given to me by Dr.C.M. Francis in every possible way. The depth of knowledge he has, on the subject was the best reference material, I could ever have. As the Coordinator of the D.H.C.A. Programme, Mr.A.K.Roy M.B.A., has been an inspiration to me to bring out this paper, I am really grateful to him.

There are others who have contributed in various ways, to make the research part of this paper possible. Among those, I would like to thankfully mention the names of Sr.Mary Clare M.Pham.,Dr.Chanda Kulkarni M.D., Dr.G.D.Ravindran M.D.,Dr.A.K.John M.S.,and Dr.Sanjiv Lewin M.D. I also appreciate the cooperation extended to me by all the faculty members of the Departments of Medicine, Surgery, Paediatrics, and Pharmacy. A big thank you to all.

Fr.Dr.Patrick Pais S.V.D.

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P A R T I

EVOLVING A RATIONAL DRUG POLICY

1. Introduction.
2. Analysis of Current Situation.
3. Definitions.
4. Rational Drug Policy.
5. Components of Rational Drug Policy.
6. Summary.

1. INTRODUCTION

India has a golden heritage in many walks of life, may it be in civilization or learning, in religion or philosophy, in science or arts. In the practice of medicine, man's total being should be the centre of concern. The ancient medical systems like Ayurveda, Sidda and Unani revolved around the question of how to restore the total human person from his ill health affecting body, mind and spirit.

With the advent of modern medicine, this healthy attitude of considering a patient as a total human person slowly dwindled. Thus today we speak of a 'heart case', a 'renal case' an'orthopedic case', etc. It is likely that in the future, the health personnel may address these cases with their International Disease Code Numbers.

Strange as it may sound, the Indian Drugs and Pharmaceutical Industry is under the supervision of the Ministry of Petroleum and Chemicals and not under the guidance and responsibility of Ministry of Health and Family welfare. The production of drugs is considered as any other industrial product. Naturally, the production of any drug whether it is a rational, irrational, hazardous, banned, bannable or simply useless becomes a measure of economic growth.

The number of production units for drug manufacture, as well as the number of drug formulations available in the market are increasing at an alarming rate. Our markets are flooded with drugs. If the number of formulations available in a country were to be the criterion, sooner of later we shall end up as a drugged society rather than a healthy community.

To avoid this catastrophy, there is an urgent need to formulate a Rational Drug Policy. It should be based on the concept of essential drugs and oriented to the needs of the people. But just by formulation of a Drug Policy one does not achieve results; what is needed is to be aware of such a policy and implement it at all levels.

In the recent years, there has been considerable interest in developing a conceptual framework leading to formulation and implementation of policies and programmes, for promoting rational use of drugs on the basis of this concept. However, it has not yet been put into practice at various levels of health care delivery.

In this paper an attempt will be made to evolve a Rational Drug Policy on the basis of rational drug use and formulate guidelines to implement it. We shall also evaluate the presciption habits of some doctors to examine, how conscientious they are in rational prescribing.

2. ANALYSIS OF CURRENT SITUATION

In order to understand the existing situation in the field of Drugs and Pharmaceuticals in India, it is necessary to look at the background. There have been some efforts in this regard.

a. The Hathi Committee Recommendations:

The Committee of Drugs and Pharmaceuticals commonly known as the Hathi Committee was appointed by the Ministry of Petroleum and Chemicals, Govt. of India. This Committee submitted its report in April 1975, with the following recommendations:-

i. Nationalization of Multinational Drug Companies.
ii. Establishment of a National Drug Authority.
iii. Priority production of 116 essential drugs.
iv. Abolition of brand names and introduction of generic names.
v. Revision and updating of National Formulary.
vi. Strengthening of quality control.
vii. Elimination of drug combinations.

I think the report submitted by the Hathi Committee and the recommendations made by it was the first ever scientific attempt to understand what was basically wrong with the Indian Pharmaceutical Industry in the context of the total health care situation in India. Indeed it was an attempt to streamline the health needs of the people of India with what was urgent and necessary. The recommendations were radical in nature and very comprehensive.

Even after fifteen years, the Hathi Committee Report is considered both within and outside India, as the most authentic and exhaustive study of Indian Pharmaceutical Industry. The Committee had made it clear that India has developed technological capacity for achieving self-reliance in drug production. The Committee recommended that the public sector should be given leadership role in drug production and that the foreign sector should be taken over by the Government. The Committee also published a list of essential drugs necessary for the management of the diseases prevalent in India and suggested measures to increase their production so as to reach the needy at a low cost.

" Unfortunately the recommendations of the Hathi Committee were largely ignored in India, whereas many developing countries have already formulated their National Drug Policies in line with the Hathi recommendations." (1)

According to all-India Drug Action Network Coordination Committee, " The Hathi Committee Report provided the inspiration for the formulation of Bangladesh National Drug Policy, yet not a single recommendation of the Hathi Committee has been implemented in India." (2)

b. National Drug Policy.

One would expect that after such exhaustive work done by the Hathi Committee the Government of India would formulate the National Drug Policy based on its recommendations. In March 1978 the National Drug Policy was promulgated with the following objectives:

i. To develop self-reliance in drug technology.
ii. To accord leadership role to public sector.
iii. To achieve self sufficiency in the production of 116 essential drugs.
iv. To encourage growth in domestic sector.
v. To ensure that drugs are available in abundance and at a reasonable price to meet the health needs of the people.
vi. To maintain high standards of production.
vii. To promote research and development.

It is claimed that the National Drug Policy is based on the Hathi Committee recommendations but they are incorporated only in bits and pieces in a very diluted form and to suit the Multinational and Indian Drug Companies rather than the genuine needs of the people.

c. <u>The Drug Price Control Order - 1979 (DPCO - 79)</u>

The Hathi Committee for the first time had recommended four categories of drug formulations for the purpose of price control. Accordingly the first DPCO - 79 promulgated the following order after classifying the drugs into four categories.

Category I - a mark-up of 40% on exfactory cost
Category II - a mark-up of 55% on exfactory cost
Category III - a mark-up of 100% on exfactory cost
Category IV - kept outside the price control.

The whole exercise was with an aim to control prices of some essential drugs carefully safeguarding the interests of the drug manufacturers.

d. The Kelkar Committee - 1987

The National Drug Policy of March 1978 was reviewed and revised by the Kelkar Committee under the chairmanship of Dr.Vijay Kelkar in 1987. The following were the main objectives:-

i. To make price control system less cumbersome but more effective by reducing the span of control

ii. To stimulate production of drugs and pharmaceuticals, which are essential to the needs of the large majority of the people of the country

iii. To ensure reasonable returns to producers of essential drugs, while at the same time restricting undue increase in their prices

iv. To ensure adequate availability at reasonable prices of essential drugs to all sections of the community, especially the weaker ones even in remote areas.

These recommendations are quite reasonable but they are very general. It did recognise the needs of the people but came out with soft and God-fatherly exhortations.

e. The Drug and Price Control Order 1987 (DPCO - 87)

The DPCO - 87 is the latest price control order, which reduced four categories of drugs into three categories for the purpose of price control.

Category I : Drugs used for six National Health programmes, namely, Tuberculosis, Leprosy, Filariasis, Malaria, Diarrheal Diseases and prevention of Blindness. In this category there are all together 26 drugs classified into these six groups. In this category a 75% maximum allowable post-manufacturing expenses is permissible. (Appendix I)

Category II : Consists of the so called " essential drugs" based on the analysis of national morbidity, drug usage pattern, trade practice and the W.H.O. model list of essential drugs of 1985. In this category a 100% maximum allowable post manufacturing expenses is permissible. It lists 139 drugs in all. (See Appendix II.)

Category III. Outside price control.

" The new drug policy announced on 18th December 1986, after long deliberations and hectic lobbying by the multinational corporations had further frustrated the attempt to generate an appropriate product structure at appropriate prices. This is because, instead of seeking a solution to the stagnation of the industry brought about by structural distor-tions, the new policy had sought a market solution and allowed a price hike to the extent of 25% for essential drugs. " (3)

In other words the Drug price control Order 1979 and 1987 have been more beneficial to the drug producers than the drug users. As AIDAN Coordinating committee put it " The National Drug Policy is formulated in such a way that it protects the financial interests of the Pharmaceutical Industry not the interests of the people."

3. DEFINITIONS USED:

Before we formulate the Rational Drug Policy it is important that we are very clear about a few concepts. These definitions are based W.H.O. Technical Report series Nos.615 & 722.

i. Efficacy:- Defined as the ability of a drug to produce the intended preventive, symptomatic or Curative effect as determined by appropriate scientific methods.

ii. Effective Drug:- An effective drug is one which, when administered in the right dose, dosage form, route, dose interval and duration of treatment, favourably modifies the clinical course of the patients disease or disorder.

iii. Benefit/ Risk Ratio:- Reflects the weighted ratio of benefit to risk in the use of a drug, a judgement concerning the role of the drug in the practice of medicine, based on efficacy and safty data, along with consideration of misuse potential, severity and prognosis of the disease, etc.

iv. Rational Drugs:- Rational Drugs are those with a demonstrated clinical efficacy and with a favourable benefit/risk ratio for defined situations and indications. These are usually recommended for use in most standard medical text books.

v. Essential Drugs:- Essential drugs are the minimum number of rational drugs and dosage forms necessary to cover preventive , symptomatic and curative health needs of the population. They should be available at all times, in adequate quantity to the people at all levels.

According to W.H.O. " The selected drugs are 'essential drugs 'indicating that they are of utmost importance and are basic, indispensable and necessary for the health needs of the population. As such these are rational , scientifically proven, therapeutically effective, ecconomical and socially accept-able."

vi. Priority Drugs:- Priority Drugs are identified among essential drugs to give priority to the major health needs of the people.

vii. Irrational Drugs:- Irrational Drugs are drugs or pharmaceuticals of unproven efficacy and safety and / or hazardous drugs. These may be single compounds or fixed dose combinations.

viii. Useless Drugs:- These are drugs and pharmaceuticals of unproven efficacy in relation to their purpose (indication) claimed, whenever adequate documentation demonstrating their clinical efficacy is missing or inadequate.

ix. Hazardous Drugs:- Hazardous drugs are those with clearly high and unfavourable benefit/ risk ratio.

4. RATIONAL DRUG POLICY

So far we have seen that there has been some attempt made by the Govt. of India in formulating and promulgating a National Drug Policy. It has only helped in commercialising health and by increasing consumerism, it has only inflated the profit margins of the drug manufacturers. We could assume that the National Drug Policy should also be a Rational Drug Policy. It has not proved to be so because it is not people oriented nor based on Essential Drugs concept. On the contrary the New Drug Policy has favoured the drug manufacturers & has only diluted the essential drug concept and has given free rein to Drug Industries to produce non-- essential drugs and formulations.

The World Health Organization has been time and again, giving guidelines to formulate National Drug Policy on the basis of Essential Drugs concept. Vide-WHO Technical Report series No. 615 and 641 on the selection of Essential Drugs and Nos. 685 (1983) , 722 (1985) and 770 (1988) on use of Essential Drugs.

The Summary of Workshop Conclusions on National Drug Policy prepared by Dr.K. Balasubramanyam. Pharmaceutical Advisor, Caribbean Community Secretariat states:

> "of the countries represented at the Asian Seminar on Pharmaceuticals, Bangladesh alone had in 1982 formulated and implemented a rational drug policy based on the guidelines recommended by the Non-aligned Summit Conference. Within a period of three

> years , the pharmaceutical supply system in Bangladesh has improved tremendously. Essential drugs are increasingly available to larger sections of the population at reduced cost. On the other hand countries which had not formulated and implemented a National policy based on essential drugs are paying very high prices for their lapse. For example the workshop was informed that in India a child was going totally blind every 13 minutes due to unavailability of Vitamin 'A '- a cheap and essential drug." (4)

That means more than 40,000 children in India become blind every year for want of Vit. 'A '.

Half of the World's T.B. Patients live in India but we produce only 1/3 of our T.B. drug requirement.

Over 60 Million people in India suffer from iodine deficiency diseases, only for want of Iodised salt.

There is no doubt that the formulation and implementation of the Rational Drug Policy is the responsibility of the Government. In view of the availability of well defined W.H.O. criteria for such a formulation, it is possible for India also to have such a Rational Policy provided it has the political will to do so.

5. COMPONENTS OF RATIONAL DRUG POLICY

a. Assessing the drug needs :-

This is the primary requirement of Rational Drug Policy. An average doctor prescribes about 40 to 50 Drugs regularly and may prescribe another 50 or so occasionally. A conscientious doctor can only prescribe drugs according to the needs of his patients. There is absolutely no evidence that a large number of drugs improves health care. On the contrary, it is known to increase the incidence of unwanted effects.

Here comes the question of Essential Drugs. The small number of drugs which suffice for almost all health needs must be identified and listed. These are the essential drugs for that community. These are sufficient to take care of all the therapeutic prophylatic and diagnostic purposes. They have to be chosen keeping in mind the benefit / risk ratio and the cost.

Hathi Committee had suggested and recommended only 116 essential drugs for India, way back in 1975. Even the latest New National Drug Policy (1987) lists only 166 drugs in the Category I & II and calls them as essential. (see Appendix I & II) . The W.H.O. estimates 250 drugs as essential. If this is so what is the rationale behind India manufacturing 60,000 or more formulations, if not for the market demand created by the Drug Industry?.

" The availability of so many different drugs, and the case of similar names for different drugs as of different names for similar drugs entails dangers for public health as well as a tremendous waste of effort and money" (5)

b. Banning Irrational and Hazardous Drugs :-

It was again the Hathi Committe that had suggested weeding out 23 irrational and hazardous drugs, which were finally banned only in July 1983 by a gazette Notification. But the sad story is that they are still available in the market. There have been time and again efforts made by a few voluntary organizations to bring an end to hazarous drugs, but they have to fight against powerful manufacturing companies and the inactivity of the drug controllers. All the same in some cases their tanacity of purpose has borne fruit. It is the Government's duty to safe guard its citizens.

We also see that many drugs banned in other Countries are dumped unscrupulously in developing countries like ours by the MNCs. Hence efforts should be made at both national and regional levels to ensure that only safe, effective and in-expensive drugs are marketed in a country.

There are about 10,000 Pharmaceutical units in India, large,medium and small size, producing about 60,000 formulations. Many of these formulations are known to be irrational and hazardous.

Most drug combinations are hazardous because:-

- They increase chances of drug interaction.
- They confuse consumers and medical practitioners alike
- They make quality control difficult.
- They increase cost unnecessarily.
- They make drug pricing and price control difficult.
- They make monitoring of adverse drug reactions difficult.

The W.H.O. list of Essential Drugs which consists of 250 drugs contain only seven combinations (Vide- Technical Report series No.722 - 1985)

C. Produce and Supply Adequately Essential Drugs:

Adequate production/ procurement and supply of essential drugs entail careful planning from the part of the Government. It has been estimated that barely 20% of the medicines available in the market today are necessary to treat 80% of the diceases. However, an anomalous situation created by irrational planning is the fact that essential drugs to treat major diseases such as T.B., Leprosy, Malaria etc. are in short supply, where as unnecessary products such as tonics and anti-diarrheals proliferate in the market.

Certain drugs must be constantly available in the market to the patients, who need them in order to maintain life and reasonable health, for example Insulin, Digoxin, Penicillin, antimalarials and anticonvalsants.

The delivery of such vital drugs to and within a country must never be interrupted, and they must therefore be supplied preferentially. They must be available to both poor and those who can afford to pay. How often we meet people who have to run from pillar to post to procure them.

d. Use of Generic Names:

The use of generic names has been recommended by UNCTAD, UNIDO, Hathi Committee and even the National Health Policy statement of 1983.

Use of Generic names has many advantages, such as

- Only generic names are used in medical, Pharmaceutical text books. All scientific medical journals and W.H.O. publications.
- Generic names ensure production, sale and dispensing of more rational single ingredient drugs.
- Generic names give class information and avoid confusion.
- Generic names are few, therefore easy to remember.
- Quality drugs under generic name are cheeper.
- Generic names will curtail heavy promotion of brands, cost of which runsinto millions, which ultimately is paid by the consumer.

The Pharmaceutical industry's main argument against generic prescribing is that the brand name guarantees the quality of the product. But brand names do not ensure quality. The United States Food and Drug Administration has shown that

branded and generic products have been substandard with equal frequency.

e. Ensure Quality:

It is estimated that one out of every five (i.e.20%) drugs is substandard and consequently dangerous and ineffective.

" There is official acceptance of the fact that 20% of pharmaceuticals produced in the country are substandard and spurious. A survey conducted in 1980 revealed that out of a total of 218 samples (of substandard production of drugs) collected, 135 substandard products were manufactured by 23 multinational companies. This gives the lie to the oft-repeated propaganda that substandard drugs are produced in small scale sector alone and that the multinationals quarantee high standards of production." (6).

The facility for quality testing in the country is woefully inadequate. There are only 600 drug inspectors in the whole country and only five Government quality control laboratories. These too lack sufficient equipment and manpower. The Government has to seriously and urgently look into this matter and take remedial measures.

f. Ensure Correct Information:

Unbiased information about both essential and non-essential drugs is required by the consumers, distributors and much more the doctors. The manufacturers have the primary responsibility to make such information available in respect to the drug produced by them. There is ample evidence that

drug producers as a rule either suppress vital information relating to their products or deliberately provide wrong information.

In India the usual practice is to ban a drug through gazette notification. But the gazette notification indicates the generic name of the drug which is banned, whereas the products of these drugs are marketed through brand names. There is usually too much ambiguity and confusion resulting in such a practice.

It is often seen that when a drug is banned or withdrawn from the market in the parent country of the pharmaceutical company which produces the product, it continue to be sold in India and often with false claims about its safety. This is sheer injustice.

g. Ensure Ethical Marketing:

> " In the absence of coherent policies and even more glaring absence of adequate monitoring and control machinery, India provides a wide open market for pharmaceutical production. The competition is fierce. The profit making objective is over-riding. Industry has no inclination or time to consider ethical alternatives. A close look at some of the practices indulged in by the pharmaceutical Industry will suffice to show that ethics is the first casual-ty of competition." (7)

India needs " to explore the possibility of establishing an entirely new set of criteria or standards governing marketing, trade, distribution, access to technology and promotion of development of national technology in the pharmaceutical sector." (8)

h. Ensure Reasonable Price Control:

India is a poor country and vast majority of people are unable to buy even the essential drugs. But Indian market is flooded with non-essential and irrational drugs. It is estimated that 90% of the 60,000 formulations available in the market are either non-essential and irrational. This is mainly because there are no legislations as to the production of non-essential drugs. The mark up of essential drugs is 75% to 100 % and non-essential even higher. This is the reason why drug companies produce excess of non-essential drugs and do not produce even the necessary essential drugs.

I think no instrument of pricing policy in itself can solve the problem of availability of essential drugs at a reasonable price unless there are stringent legislations in the production sector itself. The pricing policies have only safeguarded the interests of the industry and that too at the cost of people's health. This is absolutely unacceptable.

If our drug policy is to be rational it is incumbent on the part of the Government to first regulate the production of the essential drugs, which should be commensurate to the needs of the people and then regulate

the prices. There may be a mark up on essential drugs keeping in mind the affordability of the people and the interests of the drug industry but the mark up on non - essential drugs should be lower than the mark up on the essential drugs. There must also be a curb on the production of non-essentials, which should be always less than the essential drugs.

The licensing control prevalant in the country are just not enough to achieve the production objectives of essential drugs at reasonable prices. The open general licence cannot be a desirable means to achieve the objective of essential drug production at reasonable prices. Broadbanding is another irrational measure , which implies permitting companies to make by themselves any minor changes in multi-ingredient formulations, without the change of active ingradient. When already there are too many fixed dose irrational combinations in the market which requires elimination, such a measure will do no good. Broadbanding only leads to more drug misinformation, quality control becomes difficult and prices becomes arbitrary.

i. Promote Indigenous Research and Development:

India had allowed operation of drug Multinational corporations (MNCs) in the country, in the hope that they would either bring in scarce capital or bring high technology for production of essential life saving drugs. However, this hope has been belied.

j. Plug Legal loop Holes:

India already has several laws in force and the Government can ban import and manufacture for sale, any drug which is therapeutically irrational and involves risk to human beings and animals.

- The Drugs and Cosmetic Act 1940, later amended in 1955, 1960, 1962, 1964, 1972 and 1982.
- The Drugs and Magic Remedies Act of 1955.
- The Dangerous Drugs Act of 1930, replaced in 1985.
- The Poisons Act of 1919

"However, not withstanding the laws and the power aquired by the Government under those laws, the manufacture, import and sale of therapeutically irrational and hazardous drugs continue unabated." (9)

According to the prevalent practice it is the Drug Controller who directs the ban on manufacture or sale of any irrational or hazardous drug. But these Drug Controllers wake up only when there is a hue and cry by the public, which is so rare. Even then the courts can impose a stay order on these directions and there they lie buried. Therefore it is very necessary that there must be an independent machinery like the National Drugs Authority which should scrutinize and monitor all the drugs currently available and they must have the last say in the matter.

k. Create Awareness of Rational Drug Use:

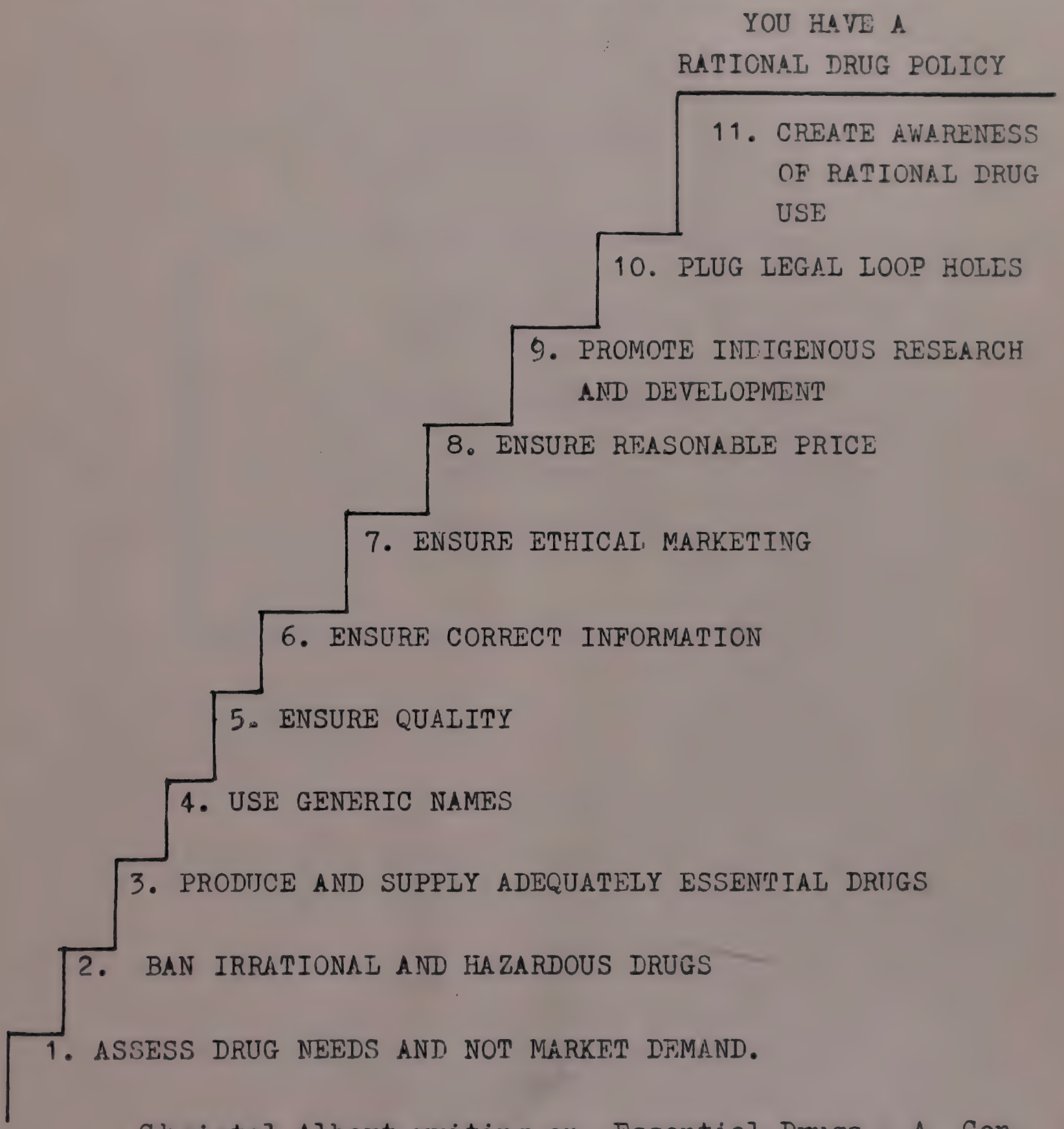
There is a lot of myth connected with drugs and therapeutics. 'A pill for every ill 'is not only practised by the drug prescribers but also vehemently and unethically promoted by the drug manufactures. Added to this is the fact of illiteracy, poverty and fear associated with the consumer who sees a doctor as a demigod. A lot has to be done to undo this impression.

We may have any number of beautifully formulated policies and statements. These will remain ineffective so long as people are unaware of their implications. A Drug Policy becomes fully operative only when it is implimented at every level. We need to create awareness of rational drug use among people of every strata of life. The drug producers with primary motive of profit making,will think little of consumers interest. It is mainly the prescribers and the users who have to be aware of the rational drug use and this is not easy especially when there is so much misinformation being forced into the minds of the people by the promotional activity of the drug industry.

The Rational Drug Policy should include elements which create awareness of the Rational Drug use among the people. So Long as this element is missing in the formulated Drug policy, the policy will remain a concept and implementation will be lacking.

6. SUMMARY

Rational Drug Policy Presented in the form of a ladder.


YOU HAVE A
RATIONAL DRUG POLICY
11. CREATE AWARENESS OF RATIONAL DRUG USE
10. PLUG LEGAL LOOP HOLES
9. PROMOTE INDIGENOUS RESEARCH AND DEVELOPMENT
8. ENSURE REASONABLE PRICE
7. ENSURE ETHICAL MARKETING
6. ENSURE CORRECT INFORMATION
5. ENSURE QUALITY
4. USE GENERIC NAMES
3. PRODUCE AND SUPPLY ADEQUATELY ESSENTIAL DRUGS
2. BAN IRRATIONAL AND HAZARDOUS DRUGS
1. ASSESS DRUG NEEDS AND NOT MARKET DEMAND.

Christel Albert writing on Essential Drugs - A Convincing Concept, gives a summary of these components in a ladder form having first ten points. I have incorporated the eleventh point, because public awareness of rational drug use only can make a Rational Drug Policy operative at the prescriber's and user's point of view.

P A R T I I

IMPLEMENTATION
OF
RATIONAL DRUG POLICY

1. Local Level.
2. National Level

IMPLEMENTATION OF RATIONAL DRUG POLICY

So far we have seen the measures taken by the Government in formulating a National Drug Policy and how we can formulate a Rational Drug Policy if we only kept in mind the good of the patients or the consumers. A National Drug Policy or A Rational Drug Policy is only a concept and remains a concept until we translate it into action. Evaluating the present practice of medicine I feel unless stringent measures are taken, the Drug Policy will not be implemented and it will always remain a concept.

I would like to divide the need for implementation mainly at two levels.

1. Local Level
2. National Level.

Although this division looks simplistic, it is necessary because at the National level one can think of the policy matters and creating conditions wherein these policy matters can be implemented at the local level. It is the local level that is most crucial because the drug use, drug procurement, storage, distribution , etc., are done at this level.

1. Local level has mainly three components:

   a. Public Awareness
   b. Health Care Personnel
   c. Health Care Institutions and Organizations.

These are interconnected and influence each other in their implementation.

a. Public Awareness:

- Public awareness movements for use of safe and rational drug use, especially by means of mass media, schools, voluntary groups, street plays, bulletins, journals, posters, radio and T.V.
- Educating the public in the misuse and over-use of injections and tonics.
- Compaign against purchase of over-the-counter drugs , which are usually costly, unnecessary and with useless ingredients often promoted by false and exaggerated advertising.
- Patients' education in effective drug use, especially about the harm caused by banned, bannable and hazardous drugs.
- Propagating the need for timely immunization, good nutrition and clean drinking water.
- Promotion of breast-feeding instead of going in for baby foods and tonics.
- Introducing health and hygine classes in all schools.
- Home visits by health personnel in educating the public, especially in the use of home remedies like tepid sponging for fever, ORT for diarrheas, saline gargles for sore throat etc.,

b. Health Care Personnel:

- Sensitizing fresh medical graduates in Rational Drug Use.
- Proper Drug Utilization
- Improving prescribing habits.
- Increasing cost consciousness.
- Promotion of non-drug therapies.
- Provision of unbiased, person-oriented drug information.
- Ill effects of polypharmacy.
- Ongoing education through clinical meetings, conferences and seminars.
- Promote correct use of medications by patients.

c. Health care Institutions and Organizations.

- Constitution of Hospital Therapeutics Committee for Reviewing the existing inventory of drugs in their pharmacy and recommend appropriate action to weed out banned, bannable, hazardous and useless drugs.
- Prepare essential drugs list for the institution. arrange procurement of drugs based on the essential drugs list prepared by the Committee.
- Prepare a Hospital Drug Formulary.
- General review and monitoring of prescribing habit of the doctor.
- Develop standard treatment regimen for local needs.
- Develop guidelines for antibiotic usage.
- Foster drug education activity in the hospital to all medical, para medical and people in general.
- Hold regular inventory of stocks.

2. National Level:

Rational Drug policy must be the basis of any National or International Drug Policy. At the National level it is the Government, which is responsible for the formulation and implementation of the Drug Policy. India's National Drug Policy is partisan in so far as it favours the interests of the drug manufacturers and not the needs of people. First and foremost a Drug Policy to be Rational should be need based and not market based.

It is high time that the Government revie.wed the entire gamut of legislation pertaining to the manufacture, selection, import ,.destribution and sale of drugs in India. Just one look at the shortage of essential drugs and abundance of non-essential drugs, shows that the National Drug Policy has not been rational and what has been formulated has not been implemented. The administrative machinery should be given adequate powers to enforce decisions. So far the Drug Controllers have been giving only advice rather than enforcing the law.

" Drug legislation should provide the following:

- A system of registration of all medical products, including traditional medicines.
- Enforcement of good manufacturing practices.
- Full control of labelling and advertising.
- Control of prices of finished drugs and therapeutic raw materials.
- prescription controll of toxic / Poisonous and habit forming drugs.

- Summary trial of violations of drug policy by manufacturers in special drug courts.
- Heavy penalties including confiscation of equipment and properties for the manufacture and/ or selling of spurious and substandard drugs. The legislation should be reviewed regularly, modified and updated in the interest of the public and they should not become bottle necks for implementation of Rational Drug Policy." (10)

ii. There is a great need to set up a National Drugs and Therapeutic Authority, which should be an independent machinary, to scrutinize all the drugs marketed in India. There can also be state level branches with clear cut duties and responsibilities to look into the proper implementation of the recommendations of the National Body. Drugs should be dealt under this National Body and not by ministry of Chemicals and Fertilizers. The recommendations of the National Body must be binding on the drug industry.

iii. Multinational Corporations (MNCs) were allowed to operate in India because India lacked high technology at that time. But now " Indian sector has developed technology to produce and thus replace 97.5 percent ie. almost the entire sales of MNCs." (11)

In this connection it is to be noted that many MNCs are misusing the loan licensing system. According to this system the MNCs empower the small scale sectors to produce drugs for them, which the MNCs will sell under their name

This helps them to transfer price and evade taxes. This should be stopped.

iv. India has technical competence to produce almost all essential drugs needed for the people. It must be made obligatory that all manufacturers produce at least 75% of the turn over to produce essential drugs and this must be increased in a phased manner. It may be necessary to give incentives to those who produce more and punish those who produce less than the stipulated percentage of essential drugs.

v. Only rational and scientifically acceptable drugs should be allowed in the market. The Government should immediately ban all irrational, useless, and hazardous drugs including all the combination drugs.

vi. The Government should lower the mark up price of non-essential drugs and keep them even lower than the essential drugs. The price of all priority drugs must be kept at the lowest level and subsidised to the weaker sections.

vii. Quality control is another important but neglected field. Stringent measures of establishing identity, strength, purity and quality of every drug manufactured must be taken. At present we have only 600 drug inspectors for the whole country. ith only five Govt. quality control laboratories for over 60,000 drugs and formulations, in nearly 10,000 manufacturing units, what kind of quality control can we expect from these? It is often seen that an occasional drug which they test for quality control if found substandard or subpotent, then by the time the notification is made, the drug will have been sold

and companies will have made undue profit. It is estimated that we need more than 8,000 drug inspectors. It can be debated if it would help just by increasing their number because of the magnitude of misuse of power for personal gain that is already present in this sector. One can easily see that if we want every drug manufactured is tested for quality before it is released to the market, the increase in number of drug inspectors is inevitable.

viii. " Our country has a large stock of health man power comprising of private practitioners in various systems like Ayurveda, Unani, Sidda, Homeopathy , yoga, Naturopathy, etc. This resource has not been so far adequately utilized".(12)

A number of traditional drugs could be advantageously used in organised health care. It is important to evaluate the use of these drugs,often their use is medically and economically justified.

ix. Use of generic names must be made compulsory. A generic name is not the exclusive property of any individual person or corporate body. " A pharmaceutical product sold under its generic name is usually cheaper than its identical or equivalent branded product." (13)

x. More emphasis and encouragement must be given to Research and Development in technology from Indigenous efforts. It may be necessary to enforce that certain percentage of the total budget (say 7%) be spent on Research and development.

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xi. A comprehensive National Drug Formulary to guide the prescription practices of doctors on the lines of British National Formulary should be immediately brought out and distributed by the Government. It should be updated every year and should contain only rational drugs.

xii. A system of continuous or periodic monitoring of the drug market to reassess the rationality of existing drugs based on the most recent medical information and results of studies and experience should be done.

xiii. A well planned drug utilization study should be conducted to assess the pattern of drug usage, the extent of its deviation from the principles of rational drug use.

xiv. A comprehensive input in medical education on rational drug use should be made with inputs in rational drug and health policies as recommended by W.H.O. and as attempted in some countries.

xv. There should be a stream-lined mechanism for evolving efficient and timely dissemination of need based drug information to health personnel and consumers.

xvi. The promotional literature should be screened and statutory provision for package inserts and their contents should be undertaken.

xvii. Consumer caution in regional language for potent drugs should be made mandatory. Warning against the use of a drug during pregnancy, in children or elderly should be depicted pictorially.

P A R T I I I

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1. RATIONAL DRUG USE
   a. Introduction
   b. Hypothesis
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1. RATIONAL DRUG USE.

a. Introduction:

Sofar we have examined as to how we could formulate a Rational Drug policy based on the concept of essential drugs and the principles of rational drug use. We have also tried to evolve a few guide-lines that would help implement the National Drug policy at the local and national levels.

This part of the paper will consist in examnining whether we have succeeded or whether we have failed to implement the National Drug policy in the daily practice of medicine.There are many aspects in the study of implementation of Rational Drug Policy like rational selection, manufacture, quality control, procurement, distribution and use of pharmaceutical products.

This paper deals with only one aspect of rational drug use from the prescribers point of view. We could also have a study of drug use from the consumers point of view. Here we are considering only the rationality or irrationality in the prescribing habits of doctors in a large Medical College Hospital.

b. Hypothesis:

It is my supposition that doctors and prescribers need to be more conscientious in their prescribing habits, if they are to practise rational drug use. One of the main reasons why there is such irrational and

unrestricted proliferation of drug formulations in the country is because doctors continue to prescribe these drugs. It is true that there is too much misuse of drugs due to over the counter purchase of drugs by the consumers. If there are too many drugs, it is because there are too many users and there are too many users because these drugs are prescribed by the doctors.

Being a teaching institution there are many internal and external constraints because of which a clear general picture may not emerge. Nevertheless, if it is proved that these doctors have need to be conscientised further into rational prescribing, then we can rightly assume that general practitioners who out number doctors in teaching institutions will need to be conscientized to a greater extent in order to form a habit of rational prescribing.

c. Scope of the Study:

The study was conducted in a large teaching institution with 750 beds, with diverse specialities. The study was restricted to only Out Patient Departments of medicine, Surgery and paediatrics. Although there are many doctors belonging to the cadres of Senior Doctors and Junior doctors, it is a sample study giving a fairly good idea of prescription habits of the doctors. Attempt was made to keep the doctors unaware of the study being conducted, so that it does not influence their prescribing pattern in any way.

Such a study also helps in knowing the prescriptions based on each individual doctors perception of the disease.

In all 490 prescriptions were critically scrutinized by experts from all three disciplines and commented upon. It was hoped that a fairly good idea will emerge as to how conscientious the doctors are in rational prescribing and rational drug use, that too in a teaching institution, where future doctors are trained.

d. METHODOLOGY :

The method followed is that of sample survey of one week's prescriptions coming to the pharmacy from out patient Departments of Medicine, Surgery and Paediatrics. All the prescription foils of Medicine, Surgery and paediatrics were marked with identifiable codes. The marking was done in such a way that it did not easily attract the attention of the prescriber.

When these prescriptions arrived at the pharmacy counter for medicine purchase, they are identified with the help of the code number and copied down as they were written on the prescription foil. Some remarks were made then and there, if a few relevant information like age and complete signature was missing.

These prescriptions were further checked with the out patient case sheet to find out if any diagnosis or impressions of the disease was mentioned or not.

Further-more the prescriptions were given to one expert each from the three departments to critically assess the prescriptions and make comments. The data thus obtained were analysed, discussed and relevant conclusions were drawn up.

2. RATIONAL DRUG USE - PRINCIPLES

a. Rational Drug Use:

i. Emphasises selective use of drugs based on:-

- Essentiality
- Safety
- Efficacy
- Easy Availability
- Low cost
- Ease of administration
- Adequate quality
- Preferably of indigenous production.

ii. Means practice of socially conscious, relevant and scientifically sound medicine.

iii. Recognises the concept of essential drugs and the concept of graded lists for different levels of health personnel.

iv. Recognises the non - drug therapy in certain conditions, the role of alternative systems of medicine and recognises the limitations of allopathic medicine in economic and other factors in the management of diseases.

v. Accepts a conscious decision to boycott certain drugs which are hazardous, bannable, or banned and use all others only when they are really needed.

vi. Means prescribing with awareness, to avoid as far as possible iatrogenesis which include

- drug induced problems
- drug interactions
- adverse drug reactions
- emerging drug resistence.

vii. Recognises the right of health personnel and consumers to unbiased drug information and its effective communication.

viii. Understands the role of drugs in the emerging health movement. (14)

Promotion of Rational Drug Use will basically consist in Rational prescribing. Rational drug prescribing requires that the medical practitioner make as accurate diagnosis as possible , select the best drug from those available and prescribe the drug in an adequate dose for a sufficient length of time, according to the standard norms of treatment. Choosing the best drug requires a judicious weighing of drug effectiveness, safety and cost. Many medical practitioners may like only effectiveness and safety to enter into the drug selection process, but cost in an important factor while use of expensive medications may be justified for life threatning illnesses, these are less common instances. Most illnesses respond to simple, inexpensive drugs and often improve with no therapy at all.

3. IRRATIONAL DRUG PRESCRIBING

" Less than opti mal prescribing practices remain a problem in public health programmes around the world, of_ten inspite of good intentions and conscientious - ness on the part of the practioners.

TYPES OF IRRATIONAL DRUG USE

Types of Irrational Drug use	Occurs if a drug is prescribed when:
i. Extravagant prescribing	- A less expensive drug would provide comparable efficacy and safety.
	- Symptomatic treatment of mild conditions diverts funds from treating serious illness
	- A brand name is used when less expensive equivalents are available.
ii. over prescribing	- The drug is not needed
	- The dose is too large
	- The treatment period is too long
	- The quantity dispensed is too great for the current course of treatment.
iii. Incorrect prescribing	- Drug is given for an incorrect diagnosis
	- The wrong drug is selected for the indication

- (Banned, bannable, hazardous and useless drugs are used.
- Adjustments are not made for coexisting medical conditions and other factors.
- Interacting drugs are prescribed
- The prescriptions are badly prepared
    - age not given
    - abbreviations used
    - Doctors signature in initials.)

iv. Multiple prescribing - Two or more medications are used. when one or less number would achieve virtually the same effect.
- Several related symptoms are treated when treatment of the primary condition will improve or cure other conditions.
- (Use of too many antibiotics together.)

v. Under prescribing
- Needed medications are not prescribed
- Dosage is inadequate
- Length of treatment is too brief." (15)

4. REASONS FOR IRRATIONAL DRUG USE

The reasons for irrational drug use may be classified into three

a. Due to Irrational Prescribing.
b. Irrational Drug Use by the Consumer.
c. Irrational Drug Production, marketing and availability.

a. Reasons for Irrational Prescribing

- Inadequate training of doctors, nurses, pharmacists and health workers
- Lack of continuing education and supervision
- Unethical medical advertising
- Prescribing for prestige and power
- Lack of time due to heavy patient load
- Fear induced prescription due to uncertain diagnosis
- Inducements by drug companies such as unethical trade discounts, bribes, gifts, sponsorships, etc.,
- Unauthorised prescribing by health workers and practitioners of other non-allopathic systems.
- Drugs used as substitute for caring.

b. Irrational drug use by the consumer

- self medication may be due to :
  - too poor to consult a doctor
  - easy availability of drugs
  - advertisements
  - peer group information
  - advice by family members.

A survey conducted by National Institute of Nutrition in twin cities of Hyderabad and Secunderabad covering 10 percent of the 330 retail pharmaceutical shops showed that self medication rate was an alarming 46 percent!

- Use of unutilized drugs
    - stopping to take medicine once the patient feels better and using them for some one who has similar symptoms.
    - Using them after the expiry date.
- Inadequate labelling or storage of medicines
    - Children having access to these may lead to accidental poisoning.
- Peer group exchange
    - Advice from relatives, friends and neighbours to take drugs which brought relief to them in similar complaints.
- Status symbol drugs
    - Unwanted use of capsules, injections and tonics.
    - Popular belief that costlier types of medicines are better.
- Multiple Consultations
    - Consultation of generalists and specialists leading to polypharmacy
    - Consultation with different system of medicine may result in potentiation and cross reactions.

- Inadequate Consumer awareness

  - Product information not given, and if available, it is in a language not understood by the consumer.(16)

c. Irrational Drug Production, Marketing and Availability.

- Industrial Policy

  - Drug policy continues to be part of the industrial policy and not part of health policy.

  - Geared to industrial growth and profit margins and not health needs of the people.

- Over abundance

  - Hathi Committee recommended 116 essential drugs.

  - WHO says 250 are essential drugs and about 600 formulations indicated in the WHO list of Essential drugs.

  - India has over 60,000 formulations!

- Quality of Drugs

  - Twenty percent of the drugs available in the country are sub-standard and spurious.

  - Many adulterated

  - Many are sold even after expiry date.

- Examples: Turmeric powder in Tetracyclin capsules, poor quality intravenous fluids. substandard Gycerol in J.J. Hospital causing 14 deaths, highlighted by the Lentin Report.

- Unwanted Drugs:

  - Banned drugs like Amidopyrine, Practolol still available.

  - Irrational Combinations. Hathi Committee suggested weeding out 23 such groups- finally banned by gazette notification in July 1983 but still available.

  - Hazardous or Bannable drugs avaialable- Example:- Analgin, Oxyphenbutazone, E.P. Forte Combination for pregnancy testing banned since June 30, 1988.

  - Costly drugs:- Drugs which are inflated in cost by inclusion of additional, often unnecessary ingradients, and packing. Tonics and high protein foods , especially baby foods.

- Wrong Priorities:-

  - Wasteful over abundant production of unimportant drugs and non-essential drugs.

  - Short supply of essential drugs, like drugs for National Control Programmes, Vit.A and Vaccines.

- Over the Counter sales

  - Due to inadequate drug legislation.
  - Even more inadequate drug control.

- Escalating Prices

  - Price control policies have been inadequate and ineffective.
  - Patients forced to buy only part of the prescription or go for substandarad drugs. (16).

A N A L Y S I S

Particulars	Medicine Nos.	(%)	Surgery Nos.	(%)	Paediatrics Nos.	(%)	Total Nos.	(%)
Total number of Prescriptions	250	(100)	90	(100)	150	(100)	490	(100)
Age/Weight mentioned	82	(32.8)	52	(57.7)	110	(73.3)	244	(49.8)
Generic (medical) name	58	(23.2)	28	(31.1)	53	(35.3)	139	(28.3)
Brand name	192	(76.8)	62	(68.8)	89	(59.3)	343	(70)
Amount Dispensed	246	(98.4)	85	(94.4)	128	(85.3)	459	(93.7)
Directions to patients	246	(98.4)	85	(94.4)	128	(85.3)	459	(93.7)
Signature in full	67	(26.8)	28	(31.1)	6	(4)	101	(20.6)
Indication	228	(91.2)	75	(83.3)	97	(64.6)	400	(81.6)
Extravagant Prescription	18	(7.2)	8	(8.8)	6	(4)	32	(6.5)
- Expensive drug	10	(4)	8	(8.8)	--		18	(3.7)
Over Prescribing	22	(8.8)	--		31	(20.6)	53	(10.8)
- Too large dose	5	(2.0)	--		22	(14.6)	27	(5.5)
- Too large treatment period	6	(2.4)	--		--		6	(1.2)
- Quantity prescribed too large	11	(4.4)	--		9	(6.0)	20	(4)

Multiple Prescribing	18	(7.2)	9	(10)	1	(0.6)	28	(5.7)
- Many unnecessary medications	8	(3.2)	18	(20)	1	(0.6)	27	(5.5)
- Treating signs and symptoms and not the primary cause	10	(4.0)	1	(1.1)		--	11	(2.2)
- Too many antibiotics		--		--	1	(0.6)	1	(0.2)
Incorrect Prescribing		--		--	3	(2.0)	3	(0.6)
- Incorrect drug for diagnosis	2	(0.8)	1	(1.1)	2	(1.3)	5	(1.0)
- Drugs given without diagnosis	3	(1.2)	4	(4.4)	4	(2.6)	11	(2.2)
- Drug interaction	2	(0.8)	5	(5.5)	2	(1.3)	9	(1.8)
- Banned/ Bannable/hazardous drug	2	(0.8)	1	(1.1)	6	(4.0)	9	(1.8)
Under prescribing								
- Dosage inadequate	5	(2.0)		--	20	(13.3)	25	(5.1)
- Duration of treatment too brief	2	(0.8)		--	5	(3.3)	7	(1.4)
Other Defects	60	(24.0)	7	(7.7)	36	(24.0)	103	(21.0)

F I N D I N G S

- 244 (50%) out of 490 O.P.D. prescriptions did not mention age or weight of the patient. Of these , the omissions were maximal in the prescriptions from the medicine department. they had not mentioned age or weight in 168 prescriptions out of 250.

- 343 (70%) of the 490 prescriptions carried atleast one brand name drug and the remaining part generic (medical) names. The paediatric priscriptions used generic names in 35% (53) of the 150 prescriptions , which was higher than the others.

- 400 (94%) of the 490 prescriptions had relevant and justifiable indications to prescribe the required drug.These prescriptions gave instructions to dispense adequate amount of drugs and also gave useful directions to the patients how they should be used.

- Only 101 of the total 490 prescriptions were found with full signatures of the doctors. From the paediatric department there were only 6 full signatures in 150 prescriptions.

- 32 (6.5%) prescriptions were extravagant with expensive tonics or other costly drugs prescribed without necessary indications. Surgery topped the list with 8 out of 90 prescriptions , closely followed by medicine.

- All together 9 prescriptions out of 490, were seen to be having bannable or hazardous drugs. Out of these 6 were from paediatrics, where certain drugs which should not be prescribed for children below certain age were prescribed.

- Over-prescribing was noticed in 37 out of 490 prescriptions. Paediatric prescriptions constituted the most with 24 of their 150 prescriptions. No incidents of over prescribing was found among the surgery prescription samples.

- There were 27(5.5%) prescriptions where doses prescribed were too large; among these 22 out of 150 were from paediatrics.

- 25 (5%) prescriptions out of 490 were with inadequate dosage, out of these 20 were from paediatrics.

- 6 prescriptions out of 250 from medicine O.P.D. had antibiotics , other than the specific ones, prescribed for very long period without proper indication for the use of these antibiotics. These were mostly prescribed along with specific anti - T.B. , anti leprosy and anti diabetic drugs. The prescriptions for antibiotics were for a month or more.

- There were 20 (4%) prescriptions given for two or three months' duration. This was noticed with regard to anti-T.B. , anti hypertensive, anti -convulsive drugs or just tonics.

- Duration of treatment was too brief in 7 prescriptions. Five from paediatrics and two from medicine.

- 27 (5.5%) prescriptions were with too many unnecessary medications, like various types of tonics and vitamines. This was particularly noticed in 18 (20%) of the 90 Surgery prescriptions.

- 10 of the 250 prescriptions from medicine and one from surgery, treated only signs and symptoms, rather than the primary underlying cause.

- One prescription from paediatrics, had two antibiotics prescribed, in a case of diarrhoea, where no antibiotics were necessary.

- There were 5 prescriptions, where wrong drugs were selected for the diagnosis. Eleven prescriptions were found, where drugs were prescribed without any diagnosis, even provisional

- In all, there were 9 (2.2%) in which drug interaction was not given attention to. Out of these 5 were from surgery.

- 103 (21%) prescriptions showed other defects, like
  - duration of treatment not mentioned,
  - timing of medication not specified,
  - dosage form not indicated,
  - fixed dose combinations used without proper indication,
  - one drug used (contrary to accepted regime) which could produce resistence.

Of these 60 (24%) out of 250 were from medicine and 36 (24%) out of 150 were from paediatric prescriptions.

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D I S C U S S I O N

In this study I have chosen a Medical College Hospital with the expectation that, it should be a place where the standards of prescribing must be very high. It is here that the doctors systematically learn, how to prescribe rationally. The three disciplines, Medicine, Surgery and Paediatrics, in which the study of prescription habits of doctors was made, also had the additional benefit of Post-graduate programmes conducted.

First of all, let us see what a correct Prescription Format is. A well written "prescription must show the following details written legibly and in ink.

a. Name of the patient,

b. Age and/or weight of the patient,

c. Hospital Registration Number,

d. Date,

e. Name of the medicine, preferably the generic or medical name, if not brand name in the formulary,

f. Abbreviations are generally not used,

g. The form of the medicine - injection, tablet, capsule, etc.,

h. The amount of medicine to be dispensed, written in metric system only, as follows

   - Above one gram - 1 g, 2g, etc.,
   - less than 1 grm, in milligram (mg) eg.500 mg.
   - less than 1 mg write preferably in microgram

i. The directions to the patients.

j. The doctors signature in full, initials not acceptable." (17)

i. Age or / and weight of the patient.

From the study it was noticed that 244(50%) of the 490 prescriptions had no age or weight mentioned. This is a serious omission. Age or weight is important to prescribe the appropriate dose. It is also important for the pharmacist to know whether the medicines are prescribed for an adult patient or a paediatric patient to dispense the appropriate amount. Certain drugs are not prescribed for the paediatric patients because their response to drugs is different from adults. This is particularly so in the neonatal period. Similarly, the amount may have to be adjusted in the case of elderly patients because of their altered absorption, metabolism and excretion.

In any case, the prescriber must state the age or the weight of children clearly in every prescription.

It is also important that the sex of the patient be mentioned in every prescription mainly because there are many drugs, which are contraindicated in pregnancy and lactation periods.

ii. Brand Names Versus Generic(medical)Names

It was noticed that 343 (70%) of the 490 prescriptions had brand name drugs. One can debate about the advantages and disadvantages of branded drugs and generic drugs. We have already discussed about the merits and demerits

of generic names when we formulated the Rational Drug policy (Vide P.15). We have seen that branded drugs or generic drugs do not in themselves gurantee quality anywhere around the world.

The manufacturer of brand products claim that they assume the legal guarantee for their products, but we know that in India there are no strict quality control measures and such guarantee becomes only a theoretical assumption.

One could argue that cost is an important factor. A brand product generally costs more than a generic product. So it is advisable to use generic names instead of a brand name for this reason and for the many reasons mentioned on P.15.

Prescription by brand name could also lead to difficulties when the drug with the particular brand name is out of stock(strikes, lockouts, problems of transport etc.,) substitution becomes difficult.

iii. Doctors Signature in Full

Many doctors either do not realise or do not think it important to put their signature in full. It is very important especially where there are many prescribers. It is important because the pharmacist or patient can go back to the doctor to clarify anything which is not clearly understood or something that is creating confusion. In our study we found only 1/5 of the total number of prescriptions with full signatures. It was particularly poor among the paediatric prescriptions, where only 6 out of 150 prescriptions had full signatures.

The doctors are legally responsible for their prescriptions, they take full responsibility for the treatment given to the patient. The initials alone are not acceptable in law.

iv. Extravagant Prescribing:

Extravagant prescribing occurs when a more expensive drug is used instead of a less expensive drug, which could provide comparable efficacy and safety. In our study we find 32 prescriptions which could be classified as extravagant. These are either expensive tonics or digestive enzymes and many containing alcohol. They are an economic waste and only " help to vitaminise our sewage systems!" In practice we find, at times doctors are pressurised by the patients and relatives to prescribe such drugs and the doctors do so to please the patients. There are occasions, when doctors having found no disease, prescribe some types of tonics just to satisfy the patient. These are truly example of irrational prescribing. The doctor should educate the people about these " junk drugs" in the market, which help not the consumer but only the drug companies. He should tell the people the need for good nutrition which is present in ordinary, cheap and locally available food, like green leafy vegetables, cereals, egg, etc., Health education is an integral part of a prescriber's responsibility. If he fails to talk about health and healthy living, he fails in his duty.

v. Over Prescribing

When a drug is prescribed unnecessarily it is considered as over prescribing. A good doctor realises that there are many complaints which do not need any drug. There is also a place for non-drug or drug-less therapy. Very often tonics and placebos are prescribed without any indication. It is necessary that the doctors are able to tell the patients that there is nothing wrong with them and they do not need any medication. Patient advice and education can be useful

Over prescribing could happen when the dose is too large, when treatment period is too long or when the quantity prescribed is too great for the current course of treatment. In the present study it was observed that 53 prescriptions of this type and of these 31 were from paediatrics. There were also a few prescriptions where antibiotics (other than th se indicated specifically for this particular condition) were prescribed for a duration of one month together with anti - T.B. drugs. It could be due to inadvert-ance, but this should not happen.

There were 20 prescriptions which were given for 2 or 3 months duration. Those include, anti- T.B. , anti- hyper-tensive and antiepileptic drugs or just simple tonics.I find this quite irrational. The reasons given for dispensing so much quantity at a time are - Patient comes for treatment from far away, any way the treatment has to be continued for morths.

I think dispensing drugs for more than a month is irrational because it is necessary for these patients to see the doctor at least once a month to ascertain the changes, if any in the condition. Some of these drugs are potentially habit forming (like phenobarbitol) and can cause drug dependence. Over dosage of some of these drugs can have dangerous consequences because of their toxicity. The storage facility in many houses is not ideal the drugs may be exposed to moisture, heat, rodents, etc., and get spoiled.

vi. Multiple Prescribing

There were 27 prescriptions out of 490 with too many unnecessary medications. They were either too many tonics and vitamins, or multiple anti-inflammatory analgesics or multiple anti asthmatic drugs. All that has been said about over prescribing and extravagant prescribing could be repeated here.

It can also happen when doctors treat only signs and symptoms instead of the underlying primary diseases as when a doctor adopts the principle of, " a pill for every ill." Some may even think it is a matter of prestige and power to prescribe a long list of drugs. All these tendencies are irrational and should be resisted by any conscientious prescriber. This is also harmful because it can give rise to drug interaction.

In the present study, 19 of the 90 prescriptions in surgery, resorted to multiple prescribing. There was only one prescription out of 150 paediatric prescriptions, where two antibiotics were used in the treatment of diarrhoea , where no antibiotic was necessary.

It is a known fact that multiple prescribing reduces patient compliance and the patient may stop taking drugs half way through the treatment and this may give rise to drug resistence.

vii. Incorrect Prescribing

There can be many reasons why prescriptions can be incorrect. The doctor may make a diagnosis and prescribe a wrong drug or a doctor may prescribe a drug without proper indication. Both these actions could be dangerous. The present study ponted out 5 prescriptions, where wrong drug was selected for the diagnosis and 11 prescriptions , where drugs were prescribed without a diagnosis. It is a very good habit, if the doctors wrote the diagnosis or at least mentioned a provisional diagnosis in the out pati-ent case sheet.

viii. Drug Interaction

It is most common when one resorts to multiple prescribing. Drug interaction could take place, as follows:

- Potentiation - e.g. Aspirin and Metaclopramide,
- Antagonism - e.g. Metaclopramide and Propanthelin,
- Alteration in drug absorption - e.g. Cimetidine and Antacids,
- Increased toxicity - e.g. Digoxin and Frusemide.

There were 9 such prescriptions. These must be avoided. They could do more harm than good.

Incorrect prescribing can occur when inadequate or subtherapeutic dose is prescribed or when the duration of the treatment is too brief. Twentyfive prescriptions had inadequate dosage, out of these 20 were from paediatrics. There were 7 prescriptions where treatment period was too brief and five of these were from paediatrics. Paediatric dosage is most often calculated according to weight of the child. If the dosage is inadequate or the treatment is too brief, the optimum therapeutic effect is not obtained, resistence can develop and an acute episode of disease can turn into a chronic one.

There were 9 prescriptions containing banned, bannable or hazardous drugs. This should never happen in a teaching institution because these doctors are supposed to be better informed. There are some drugs which are explicitely contraindicated for children. This is because there is greater risk of toxicity in children due to:

- deficient metabolic processes
- inefficient renal clearance
- different organ sensitivities and
- inadequate detoxifying systems.

ix. Other Defects :

There were 103 prescriptions out of 490 which had various types of defects other than those mentioned above. We shall discuss them one by one.

i. Duration of treatment not mentioned. It is the doctor who decides how long the treatment should continue according to the type and severity of the disease. If it is not specified in the prescription, how can the pharmacist know what amount is to be dispensed? It is also necessary that the dosage form, and the number of daily doses has to be written on the prescriptions, if the treatment has to be effective. If the dose is too small it will not have the therapeutic effect and if it is too large there is the danger of toxicity and other adverse reactions.

ii. The pharmacist cannot know how much to dispense if the doctor writes " when necessary." The same could be true when he writes " one bottle" because bottles come in different sizes. The amount should be mentioned clearly.

iii. Timing of taking the drugs is also important. Some drugs are taken before meals and some after meals, some before going to bed and some on empty stomach, some every 8 hours and some every 6 hours etc,. Timing helps in deriving the full benefit from the drug.

iv. Fixed dose Combination Drugs

There are too many fixed dose combination drugs in Indian markets and there is stiff competition among different companies to push their products. This only confuses to doctor and confounds the consumers. The companies argue that combination drugs increase patient compliance, a single formulation takes care of several complaints and are cheaper than several single ingradient drugs. Many of these fixed dose combination drugs are simply irrational because :-

- They increase chances of drug interaction
- All the ingradients in a formulation may not be indicated.
- Difficult to monitor the adverse reactions
- Unnecessarily increase the cost.
- Quality control becomes difficult
- the biological half-lives of the components may be very different affecting the availability and concentration of the drug.
- many of them contain ingredients in quantities lower than therapeutically necessary, making them useless and even harmful.
- Often doctors are unaware of the contents of these combinations because they are so many.
- Very often some components are unnecessary eg. Fixed dose combinations of vitamins. The requirements of vitamins should be determined for a particular deficiency.
- Lack of flexibility in adjusting the dosage to suit the patient need.
- Some are outright irrational like Benzodiazepines plus analgesics and anti-inflammatory steroids.
- It is often a form of shot gun therapy.

It is therefore, important for the practitioner not to get influenced by the 'claims' made by the companies or to succumb to the temptation of prescribing the 'latest in the market' in prescribing the combination drugs. It is always wiser to prescribe single ingredient drugs in the required amount and combine more drugs if they are justifiably indicated.

RECOMMENDATIONS

The findings from the study made in this teaching hospital has revealed many omissions, shortcomings, mistakes and failures in the practice of National Drug prescribing and thus, in turn, in the National drug use. There is scope for much improvement.

The following are few suggestions and recommendations, I would like to make with the hope that they will help towards the practice of National prescribing.

a. Individual prescriber level: The prescriber should:

- follow the standard prescription format conscientiously,
- Adhere to standard National prescribing only,
- Use only generic names and those branded drugs given in the Hospital Formulary.
- Be specific with regard to the dosage, dosage form, amount, timing and duration of treatment.
- Know what you are prescribing. Be clear about drug interactions, adverse reactions, indications, contra-indications and specific precautions of all drugs one is prescribing.
- Realise the importance of non-drug therapy and simple household remedies.
- Form a habit of writing the signature in full at the end of the prescription.
- Be up to date with banned, bannable, hazardous and useless drugs and never prescribe them.

- Educate patients with the correct use of drugs and give nutrition advice to those who pressurise doctors into prescribing tonics and baby foods.
- Be cost conscious in prescribing
- Always look for current drug information
- Avoid shot gun therapy
- Do not prescribe combination drugs as far as possible
- Never prescribe for prestige or power.
- Do not get carried away by the promotional activities of the company representatives.
- After writing a prescription read through it once and ask yourself is this prescription necessary?

b. Institutional level:

The institution can assist the prescriber in rational prescribing in a big way . If the management philosophy is attuned to rational drug use, it will create a conducive atmosphere, where the practitioner can practise rational prescribing. One of the foremost requirement is that adequate training must be given to the medical students and the medical practitioners.

First of all the management should establish an efficient Hospital pharmacy and therapeutic committee, which should be charged with the duty of selecting the necessary drugs for the Hospital Formulary. The committee should lay

down prescribing policies for all its practitioners.

The Hospital pharmacy and Therapeutic Committee can then develop standard treatment norms for common illnesses in the area. The following are the general guidelines:

- Limit amounts dispensed at one time to reduce abuse and wastage.
- Educate the practitioners in Rational prescribing.
- Stimulate drug education activities among hospital staff.
- Set guidelines for antibiotic use.
- Instruct, supervise and monitor the prescribing practices of the new graduates.
- Arrange drug update seminars and conferences.
- Encourage generic prescribing.
- Discourage non-formulary prescriptions.
- Conscientize practitioners to cost consciousness
- Select and procure only standard quality, drugs
- Make avaialble periodicals, bulletins and journals on drug information.
- A large teaching institution should plan to have its own quality testing laboratory.
- Establish an information system to notify any adverse drug reactions to the staff.

C O N C L U S I O N

Our study has adequately shown that there are so many areas, where prescription habits of the doctors can be improved. We have noticed that there is so much negligence in the way prescriptions are written which need to be refined. Some do not write the age or weight of the patients, others do not sign their names in full and still others do not specify the duration of the treatment.

There is also a lot of irrational prescribing due to extravagant prescribing, over prescribing, under prescribing, multiple prescribing and incorrect prescribings. In all these instances their number is quite significant.

There is need to cut down the use of fixed-dose combination drugs and take precaution about the drug interactions while prescribing.

All these anomalous situations in prescribing, points to the obvious factor that " the doctors and prescribers need to be more conscientious in their prescribing habits, if they are to practise rational drug use." (Vide, Hypothesis P. 34.). That was the hypothesis on which we began this study.

It is true one cannot generalise it to a wider extent because the study done is limited to one teaching hospital and that too only to three of its outpatient departments. Neverthless, it is an indicator of the existing prescribing habits of the doctors.

We could also, further more, conclude that if this is the situation in a teaching hospital where future doctors and other health personnel are trained and where prescribers have a better chance of being informed about day to day developments in Pharmacology and medicine, Then what can be said about the vast majority of general practitioners, who generally have no access to such information?

Finally let us not put all the blame on the unscrupulous drug manufacturers and the uncaring Government, for whom Rational drug use means little, the practitioners themselves have to be blamed for flouting, (some even consciously) the principles of Rational drug use by their irrational prescribing habits.

Drugs have played an important role in human history. They have allayed pain and suffering. They have helped many to live more comforatable, productive and meaningful lives. But we have seen that if we are not conscientious in their use they can cause undue and unwanted harm.

It is the responsibility of everyone to promote Rational Drug Use, not only the prescriber, but also the consumer and the manufacturer. And this can only happen when we have a Rational Drug Policy which is based on the concept of Essential Drugs and is oriented to the real needs of the people.

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APPENDIX . I

Category I drugs

I. NATIONAL T.B. ERADICATION PROGRAMME

1. Streptomycin
2. Isonazid
3. Thiacetazone
4. Ethambutol
5. Sodium PAS
6. Zyrazinamide
7. Rifampicin

II. NATIONAL LEPROSY ERADICATION PROGRAMME

1. Dapsone
2. Clofazimine
3. Rifampicin

III. NATIONAL TRACHOMA CONTROL PROGRAMME AND NATIONAL PROGRAMME FOR CONTROL OF BLINDNESS

1. Tetracycline Hydrochloride
2. Sodium Sulphacetamide
3. Pilocarpine
4. Hydrocortisone
5. Idoxuridine
6. Timolol
7. Acetazolamide
8. Atropine
9. Homatropin

IV. PROGRAMME FOR PREVENTION OF DEHYDRATION UNDER CRT

1. Oral Rehydration Salt

V. NATIONAL MALARIA ERADICATION PROGRAMME

1. Chloroquine
2. Amodiaquine
3. Quinine
4. Pyrimethamine
5. Sulfamethoxypyrazine
6. Paracetamol

VI. NATIONAL FILARIA ERADICATION PROGRAMME

1. Diethyl Carbamazine

APPENDIX II

Category II Drugs

1. Aspirin
2. Amoxycillin
3. Ampicillin
4. Amiloride
5. Aluminium Hydroxide
6. Amitryptyline
7. Aminophyline
8. Baralgan Ketone
9. Bephenium
10. Benzathine Benzylpenicillin
11. Betamethasone
12. Chlorpheniramine
13. Cyproheptadine
14. Carbamazepine
15. Chloroquin
16. Cephalexin
17. Chloramphenicol
18. Cloxacillin
19. Cetrimide
20. Cimitidine
21. Carbamizole
22. Chlorpromazine
23. Calcium Pentathenate
24. Chlorhexidine
25. Dextropropoxyphene
26. Dexamethasone
27. Diazepam
28. Dehydroemitine
29. Diloxamide
30. Doxycycline
31. Digoxin
32. Dihydralazine
33. Dipyridamole
34. Dopamine
35. Dichlorometaxylenol
36. Diphenoxylate
37. Epinephrine
38. Ethosuximide
39. Erythromycin
40. Ethionamide
41. Ergotamine
42. Ergometrine
43. Ephedrine
44. Framycetin
45. Folic Acid
46. Frusemide
47. Flurazepam
48. Furazolidone
49. Gentamycin
50. Griseofulvin
51. Glyceryl Trinitrate
52. Glibenclamide
53. Hydroxycobalamin/Cynocobalt
54. Heparin
55. Hydralazine
56. Hydrochlorothiazide
57. Hydrocortizone
58. Hepatitis - B Vaccine
59. Ibuprofen
60. Iodochlorohydroxyquinoline
61. Iron Dextran
62. Isoprenaline
63. Isosorbide Dinitrate
64. Insulin
65. Imipramine
66. Ketoprofen
67. Lidocaine/Xylocaine
68. Levamizole

69. Loperamide
70. Lorazepam
71. Metamizole (Analgin)
72. Mebhydroline
73. Metronidazole
74. Methyl Dopa
75. Metaclopramide
76. Menthol
77. Methyl Salicylate
78. Nalidixic Acid
79. Nitrofurantoin
80. Nitrazepam
81. Oxytetracycline
82. Oxytocin
83. Oxythazine
84. Oxazepam
85. Pentazocine
86. Piroxycam
87. Probenecid
88. Pheniramine
89. Prednisolone
90. Prochlorperazine
91. Phenobarbitone
92. Phenytoin
93. Piperazine
94. Pyrental
95. Penicillins
96. Phenoxymethylpenicillin
97. Procaine Benzylpenicillin
98. Propionamide
99. Pentamidine
100. Primaquine
101. Procainamide
102. Parachloro Meta Xylenol
103. Promethazine
104. Quinidine
105. Reserpine
106. Ranitidine
107. Salazosulfapyridine
108. Sulphadimidine
109. Sulphacetamide
110. Sulphadiazine
111. Sulphamethiazole
112. Sulphamethoxazole
113. Sulphaphenazole
114. Sodium Stibogluconate
115. Sulphadoxine
116. Sodium Nitroprusside
117. Spiranolactone
118. Silver Nitrate
119. Salbutamol
120. Tetramizole
121. Thiabendazole
122. Tetracycline
123. Trimethoprim
124. Triamterene
125. Trifluperazine
126. Triflupromazine
127. Terbutaline
128. Theophylline
129. Valproic Acid
130. Verapamil
131. Vitamin A
132. Vitamin B 1
133. Vitamin B 2
134. Vitamin B 6
135. Vitamin C
136. Vitamin D
137. Vitamin E
138. Warfarin
139. Xanthinol